



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re the application of:

Bach et al.

Serial Number: 09/845,489

Filed: April 30, 2001

Entitled: MICRO-ARRAY

EVANESCENT WAVE

FLUORESCENCE DETECTION

DEVICE

) Art Group: 1641

) Examiner: Jacob Cheu

BRIEF ON APPEAL

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This appeal is taken from the final rejection of all claims pending in this application, claims 90-94 (See Appendix).

The notice of appeal to the Board of Patent Appeals and Interferences was timely filed by first class mail on June 21, 2006. A final office action was issued March 24, 2006.

APPEAL BRIEF

This is an appeal to the United States Patent Office Board of Patent Appeals and Interferences re application number 09/845,489 filed April 30, 2001.

I. Real Party of Interest

The real party of interest is the assignee Edgelight Biosciences Inc. of 44 Codman Dr., Sudbury MA 01776.

II. Related Appeals and Interferences

There are no other related appeals or interferences.

III. Status of the Claims

Claims 1-89 (cancelled).

Claims 90-94 (previously presented) currently being appealed.

Claims 95-101 (cancelled).

This appeal is taken with respect to Claims 90-94 which are pending and have been finally rejected. Claim 90 is independent with claims 91-94 depending on it. Claims 90-94 should be considered as a group. Claims 90-94 stand or fall together.

IV. Status of Amendments

No amendments have been filed subsequent to the examiner's final rejection of March 24, 2006.

V. Summary of Claimed Subject Matter

The present invention provides a way of constructing biological test units where target substances can be detected in fluid samples. Any biological material might be a candidate target substance with viruses and microbes being especially interesting. The invention becomes a fully functional, disposable chemistry platform for the testing and detection of molecules of biological interest. The present invention finds many other uses in biotechnology. (See Background of the Invention, especially pp. 3-13).

The claimed subject matter concerns nanowell micro-arrays in optical contact with polymer waveguides where the nano-wells are located in the cladding of the waveguide itself. Light propagating in the core of the optical waveguide has an evanescent field in the cladding around the core. This evanescent field interacts directly with the nano-wells. Fluid samples can be placed in the nano-wells or conveyed into the nano-wells by microfluidic structures. The presence of a biological target substance in fluid samples can be captured on the waveguide surface using, for example, DNA capture probes and then be detected by sensing fluorescent radiation generated by fluorescent tags bound to the target substances. The fluorescent tags generate fluorescent radiation as a result of their excitation close to the waveguide surface by the evanescent field. A detector located at the side of the waveguide opposite the nanowells can detect this fluorescent radiation signaling the presence of a target substance. (See abstract and pp. 15-16 specification).

A possible use of the invention is to attach DNA or RNA sequences of target substance on the waveguide surface located in the nanowells. Each well can contain a different sequence of interest. The nanowells can be prepared with tagged DNA samples so that any target DNA present in the fluid to be tested (like a virus) will bind to one of the DNA sequences in the nanowells. The nanowells can be flushed so that all unbound tagged samples are removed. This leaves only the tagged samples. The present invention then allows detection and counting of the remaining bound samples by injecting light from a laser or other source into the polymer waveguide. The evanescent light wave in the waveguide cladding causes the remaining tagged samples to fluoresce.

Figure 1 shows a diagram of an embodiment of the invention. Light passes through a polymer waveguide that contains micro-arrays of nanocells **30**. Bound tagged molecules **31** fluoresce and emit detectable light **32** when excited by the evanescent wave of the main light beam.

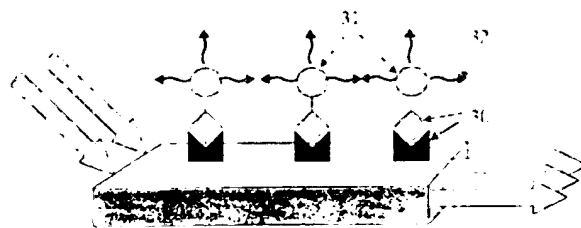


FIGURE 1

Figure 2 shows laser light **12** entering a polymer waveguide with a core **11** and a cladding **13**. The evanescent wave in the cladding **13** can excite fluorescent tags in a nanowell **14** causing the tag to fluoresce and emit different light **10** that can be detected by a detector **16**.

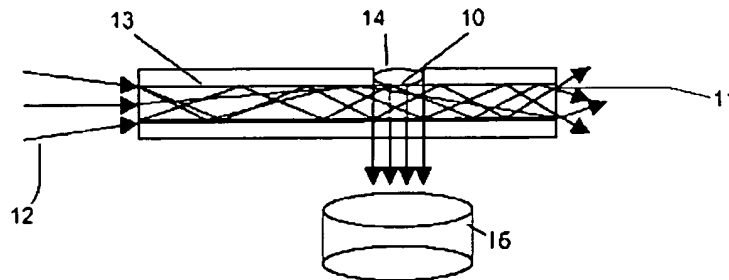


FIGURE 2

VI. Grounds of Rejection to be Reviewed on Appeal

Claims 90-94 stand rejected under 35 U.S.C. §102(e) as anticipated by Pfof et al. (U.S. 6,485,690) as evidenced by Murray et al. (U.S. 4,752,115).

VII. Argument

I. Issue:

Whether claims 90-94 are anticipated by the Pfof reference.

II. Introduction:

Claim 90 claims a structure that is comprised of a top outer layer, a fluidics layer, a first cladding layer, a waveguide core layer and a second cladding layer. An evanescent wave travels in the cladding layers. The examiner has rejected this claim (and its dependents 91-94) under 35 U.S.C. §102(e) as being anticipated by Pfohl et al. (U.S. 6,485,690) even though the examiner admits that Pfohl does not contain the two cladding layers or the core layer. The examiner cites Murray et al. (U.S. 4,752,115) as "evidence" that Pfohl's one word reference to "fiber optics" encompasses these elements as claimed.

III. The Legal Standard for Anticipation

"A person shall be entitled to a patent unless --- the invention was described in ... (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, ..." 35 U.S.C. §102(e). Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference or embodied in a single prior art device or practice. In re Paulson, 30 F.3d 1475, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994); In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990). The corollary of the rule is that absence from the reference of any claimed element negates anticipation. Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 230 USPQ2d 81 (Fed. Cir. 1986). Anticipation requires that the claim reads on the prior art reference. Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 51 USPQ2d 1943 (Fed. Cir. 1999). In order to anticipate, a prior art reference must be enabling. It must place the disclosed matter in possession of

the public. Akzo N.V. v. United States ITC, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986); Ashland Oil, Inc. v. Delta Resins & Refracs., Inc., 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985). The reference must describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the field of the invention in possession of it. See In re Spada at 708.

While all of the elements of the claim must be found in a single reference, additional references may be used to interpret the allegedly anticipating reference and shed light on what it would have meant to those skilled in the art at the time. Studiengesellschaft Kohle v. Dart Indus., Inc., 726 F.2d 724, 220 USPQ 841 (Fed. Cir. 1984). It is appropriate to look at a second reference to see whether the first gives possession of the invention to a person of ordinary skill in the art; however, anticipation does not permit an additional reference to supply a missing claim limitation.

"Although we have permitted the use of additional references to confirm the contents of the allegedly anticipating reference, we have made clear that anticipation does not permit an additional reference to supply a missing claim element." Teleflex Inc. v. Ficosa North Am. Corp., 299 F.3d 1313, 1335, 63 USPQ2d 1374 (Fed. Cir. 2002).

IV. Claims 90-94 are novel over the Pfohl et al. reference

The applicant agrees with the examiner that a waveguide core enclosed between two cladding layers would be understood by a person of ordinary skill in the art as a possible form of fiber optic structure or optical waveguide. The applicant has so-stated in the specification. The applicants also agree with the examiner that the Murray Jr. reference describes an optical waveguide.

The applicant disagrees with the examiner (and hence appeals to the Board) that the Pfof et al. reference anticipates claims 90-94 of the instant application under 35 U.S.C. §102(e). The novelty of the applicant's invention lies in combining a special type of optical waveguide with a microfluidics system. Pfof et al. is missing the most critical limitations of the applicants' claims, namely any type of optical waveguide (which requires an optical core layer and two optical cladding layers). Pfof contains neither a first cladding layer, a waveguide core nor a second cladding layer required by claim 90. This is admitted by the examiner on page 3 of the current rejection: "Although Pfof et al. do not explicitly disclose the details of the fiber optic structure, it is well known to one [sic] ordinary skill in the art that the fiber optics are composed of two cladding layers and a waveguide core as evidenced [sic] Murray et al." This statement is technically wrong! Most fiber optics in practice today are circular and use only a single cladding layer wrapped around a circular core.

The examiner relies on the single statement in Col. 11, line 40-55 of Pfof:

"Also, any of the layers in the processor can incorporate electronic or optical elements including, for example, transistors, memory cells, capacitors, resistors, LED's, fiber optics," (emphasis added).

The applicant believes that Pfof is merely stating that some arbitrary layer or layers in his processor can incorporate fiber optics. However, Pfof does not disclose any structure or detail of how this can be done. This is not sufficient for a rejection under 35 U.S.C. §102(e). While a second reference can be used in an anticipation rejection to evidence what is inherent in a particular structure or system; it cannot be used to supply a missing element. See Teleflex Inc. at

1335. A person of ordinary skill in the art could interpret Pfof's statement to mean that any one of his layers could contain some sort of embedded fiber optics; nevertheless, Pfof simply does not teach putting nanocells into the cladding layer of a layer fiber optic waveguide to be excited by an evanescent wave. A layered fiber optic structure with embedded nanocells is also not inherent in the system of Pfof or in the subject matter claimed by the applicants. Rather it is a novel teaching of the applicant's invention. Additionally, Pfof totally fails to teach an evanescent wave as required by claim 90.

In addition to not teaching a multi-layer optical waveguide that uses an evanescent wave, Pfof's layers have totally different uses:

"The processor 10 includes a top plate or layer which is also called a reagent reservoir 12. The processor 10 also includes a middle plate or layer¹⁴ (also called a fluidic delivery or distribution layer), as well as one or more bottom layers or well plates 16." (Col. 5, lines 57-61).

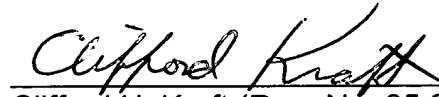
Pfof's top layer contains reagents. This is totally different in structure and function from an optical waveguide cladding. Optical waveguide claddings and cores must have a particular range of refractive index, and a particular relationship between the refractive index of the cladding and that of the core to produce total internal reflection as taught by the applicants (and is well known in the art). The applicants' claim 90 claims 3 distinct waveguide layers in addition to a fluidics layer as well as the use of an evanescent wave. The difference can be particularly noted in that Pfof allows his layers to be plates. A plate cannot be substituted for a cladding or core layer of an optical waveguide. Pfof teaches five-layer and other structures, but Pfof nowhere mentions an optical waveguide core or cladding, nor does Pfof even hint at an evanescent wave technology.

Conclusion

The Appellant respectfully submits that the Pfoest et al. reference fails to anticipate the claimed invention, and that the Murray et al. reference does not cure this deficiency. There are numerous references such as Murray that the examiner could have chosen to describe an optical waveguide, none of them describe the applicant's particular invention of an optical waveguide with nanocells embedded in a cladding layer, and an evanescent wave in the cladding layer that excites molecules in the nanocells.

Since the Pfoest et al. reference does not anticipate independent claim 90, it cannot anticipate dependent claims 91-94 each of which contains additional limitations.

Respectfully submitted

A handwritten signature in cursive script, reading "Clifford Kraft", written over a horizontal line.

Clifford H. Kraft (Reg. No. 35,229)
Attorney of Record

I. Claims Appendix

Claims on Appeal

Claim 90. A laminar biosensor comprising:

a top outer layer containing at least one fluid port;

a fluidics layer below said top outer layer containing at least one fluidics channel in fluid communication with said fluid port;

a first cladding layer below said fluidics layer containing at least one micro-cuvette in fluid communication with said fluidics channel;

a waveguide core layer containing at least one channel waveguide core in contact with said micro-cuvette;

a second cladding layer below said waveguide core layer in contact with said waveguide core;

an excitation light source optically coupled into said waveguide core layer;

whereby, fluid containing samples and optical tags placed in said fluid port is transferred by said fluidics channel into said micro-cuvette where light

from said excitation light source enters said micro-cuvette by means of an evanescent wave in said first cladding layer exciting any of said optical tags binding to target molecules in said micro-cuvette.

Claim 91. The laminar biosensor of claim 90 further comprising a plurality of micro-cuvettes in said first cladding layer.

Claim 92. The laminar biosensor of claim 90 further comprising a plurality of channel waveguide cores in said waveguide core layer.

Claim 93. The laminar biosensor of claim 90 further comprising a bottom supporting layer below said second cladding layer.

Claim 94. The laminar biosensor of claim 93 wherein said bottom supporting layer is optically transparent to light produced by said optical tags.

II. Evidence Appendix

NONE

III. Related Proceedings Appendix

NONE

Notification of Non-Compliant Appeal Brief
(37 CFR 41.37)

Application No.

09/845,489

Applicant(s)

BACH ET AL.

Examiner

Jacob Cheu

Art Unit

1641

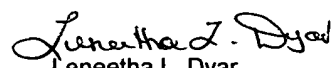
The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on 18 August 2006 is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file an amended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer.
EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.

1. ☒ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.
2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).
3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).
4. ☐ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).
5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi)).
6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).
7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).
8. ☒ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).
9. ☒ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).
10. ☐ Other (including any explanation in support of the above items):

8. and 9. Evidence Appendix and Related Proceedings Appendix: These sections are missing from this brief. If nothing is being submitted with these sections, an indication of "NONE" is required.


Leneetha L. Dyar
Patent Appeals Specialist

This paper is being submitted by United States First Class Mail with sufficient postage addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on:

Date: SEPT. 18, 2006

Signature: Clifford Kraft

Name: **Clifford H. Kraft**